Remarks

Claims 1, 2 and 11-15 are pending. Claims 1, 2 and 11-14 have been amended. Support for the foregoing claim amendments may be found throughout the specification, for example at page 18, lines 3-25, in the sequence listing, and in the original claims. The specification has been amended at the request of the Examiner to remove alleged embedded hyperlinks. No new matter enters by these amendments. Upon entry of the foregoing amendments, claims 1, 2 and 11-15 are pending in the application.

I. Status

An appeal brief was filed on June 30 2003. The Examiner indicates in the Office Action, however, that "[I]n view of the appeal brief... PROSECUTION IS HEREBY REOPENED with the instant Non-Final Action." Office Action at page 2. Moreover, the Examiner indicates that the "rejections and/or objections are either reiterated or newly applied." *Id.* The Examiner also requires the Applicant to either: "(1) file a reply under 37 CFR 1.111...; or (2) request reinstatement of the appeal." *Id.* Applicants acknowledge that prosecution has been reopened in the present Office Action and Applicants submit the instant amendment and response under 37 CFR 1.111.

II. Rejections under 35 U.S.C. § 101

Claims 1, 2 and 11-15 were rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well-established utility. Office Action at page 3. Applicants respectfully traverse this rejection.

The Examiner acknowledges throughout the Office Action that the specification describes multiple utilities for the present invention, including "identifying promoters involved in gene regulation," "determining whether a plant contains a mutation," "acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function," "identifying the presence or absence of a polymorphism," and "as probes for other molecules or as a source of primers." *Id.* at pages 3-12. However, despite this acknowledgement and numerous additional uses cited throughout the specification, the Examiner contends that none of these utilities constitutes a "specific" or "substantial" utility. *Id.* at pages 2-13. In particular, the Examiner alleges that the disclosed utilities are "generally applicable to any polynucleotide." *Id.* at page 3. In addition, the Examiner contends throughout the Office Action that many of the disclosed utilities would require further experimentation to confirm the utility. *See, e.g., Id.* at page 7.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence or absence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, *etc.* S*ee, e.g.,* specification, beginning at page 33, line 24, under heading "Uses of the Agents of the Invention".

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a

microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are "generally applicable to any polynucleotide." Office Action at page 3. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

Moreover, the specification also discloses the isolation of the claimed nucleic acid molecules from the cDNA library LIB3280 and that such cDNA library was prepared from *Triticum aestivum* anthers harvested from plants which reaches anthesis at the split boot stage. Specification at page 33, line 25 through page 34, line 1. In addition, the specification describes that such sequences will enable the isolation of agronomically important genes "associated with plant growth, quality and yield and could also serve as links in important developmental, metabolic, and catabolic pathways." *See, e.g.,* specification at page 34, lines 9-11, in the Examples at page 86, *et seq.* and in the Sequence Listing. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify polymorphisms and markers and isolate promoters in wheat plants upon reading the present specification. These

utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner further states that the credibility of the presently asserted utilities has not been assessed. Office Action at pages 4 and 12. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In fact, the very citation used by the Examiner, quoting the current USPTO utility guidelines states that "Office personnel *must* determine if the assertion of utility is credible." Office Action at page 4 (emphasis added). Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the

credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

III. Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1, 2 and 11-15 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, if the utility of a claimed invention is not disclosed, one skilled in the art clearly would not know how to make and use said claimed invention). Office Action at pages 4 and 12-13. Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility.

IV. Rejections under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1, 2 and 11-15 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

at the time the application was filed, had possession of the claimed invention." Office Action at page 13. Applicants respectfully traverse this rejection.

The Examiner, acknowledges that "SEQ ID NO: 1, per se meets the written description provisions of 35 USC 112, first paragraph." *Id.* However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that the claims allegedly encompass nucleic acid sequences encoding full-length open reading frames for which no written description is provided in the specification. According to the Examiner, the sequences recited in the claims appear to comprise a partial reading frame and "[t]he specification has provided no teachings as to a function for a protein encoded by isolated SEQ ID NO: 1 and provides no description of the remainder of the coding sequence of which SEQ ID NO: 1 is a fragment." *Id.* Apparently, the Examiner contends that "[t]he structure of the full-length coding sequence is not taught by the specification yet the claims encompass such." *Id.* Applicants respectfully traverse.

The Examiner cites to short fragments of several GenBank Accessions to apparently support the proposition that "the breadth of the claims is very large to which there is insufficient description in the specification." Office Action at page 14-15. However, none of the cited sequences comprise SEQ ID NO: 1 or complement thereof, or comprise the claimed identity to SEQ ID NO: 1.

It is well-established law that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon*

Research Corp. v. CBS, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are not specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head by requiring Applicants to describe hypothetical claim elements. The claims recite the required nucleic acid sequences and recite percent sequence identities. Applicants' claims do not recite reading frames and, accordingly, need not describe them. Applicants need only describe the claimed invention, and have done so in the present application.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 1, and the complements and variations thereof. Applicants have indeed demonstrated possession of the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, and so forth (*see, e.g.,* specification at page 19, line 16 through page 20, line 9; page 25, line 12 through page 28, line 25; and page 37, line 1 through page 47,

line 2). The specification also describes appropriate hybridization conditions (*see, e.g.,* specification at 18, line 3 through page 19, line 16); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 22, line 3 through page 25, line 5); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 29, lines 18-24); plant homologue proteins (*see, e.g.,* specification at page 29, line 25 through page 30, line 14); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 57, line 13 through page 58, line 24); vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.,* specification 62, line 14 through page 79, line 8); and construction of cDNA libraries using the claimed nucleic acid molecules (*see, e.g.,* specification at page 86, line 25 through page 89, line 11 (Examples 1-2)).

Thus, Applicants respectfully disagree with the Examiner's contention that despite the numerous variations of the claimed nucleic acid molecules described in the present specification, "the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation." Office Action at page 16. The test, promulgated by the Federal Circuit, stipulates that where a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus, written description is satisfied. *See, Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In the present case, Applicants have satisfied that test for written description

by providing a structural feature, namely nucleic acid molecules that distinguish members of the claimed genera from non-members.

Applicants maintain that they have provided a representative number of detailed chemical structures, for example, the nucleic acid sequence of SEQ ID NO: 1, and the complete complement. The common structural feature (the nucleotide sequence of SEQ ID NO: 1 and it's complements) is shared by every nucleic acid molecule in the claimed genera, and this feature distinguishes members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. Accordingly, the standard elucidated in *University of Cal. v. Eli Lilly* for the written description requirement has been met.

Moreover, closely related nucleic acid molecules falling within the scope of the present claims are readily identifiable - they either share the recited percent sequence identity to SEQ ID NO: 1 (or complements thereof) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that,

as of the filing date sought, that applicants were in possession of the invention as now claimed. See, *e.g.*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), M.P.E.P. § 2163.02. The Examiner has failed to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that Applicants were in possession of the invention as claimed in view of the disclosure of the application as filed.

The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants' has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Based on the foregoing, Applicants respectfully submit that the currently pending claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112. As such, reconsideration and withdrawal of the outstanding written description rejection are respectfully requested.

V. Rejection under 35 U.S.C. § 112, Second paragraph

Claims 1, 2 and 11-15 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly "being indefinite for failing to particularly point our and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 19. Applicants respectfully traverse.

Claims 1 and 2 are allegedly indefinite in the recitation of the phrase "fragment thereof" because "it is unclear whether the 'fragment thereof' refers to a fragment of the encoded protein or a fragment of the isolated nucleic acid molecule." Office Action at page 19. Applicants respectfully disagree. However, in order to facilitate prosecution, Applicants have amended Claims 1 and 2 to eliminate the recitation of "fragment thereof." Applicants respectfully request withdraw of the 35 U.S.C. § 112, second paragraph rejection of claims 1 and 2.

Claims 11-14 are allegedly indefinite in the recitation of the phrase "complement thereof" because "[a] possible interpretation is that the complement must be of the same length and be the full and exact complement of the recited sequence. Another interpretation is that any complement is meant including those with less than 100% complementarity, such as 90%, 50% or even 10%." *Id.* Applicants respectfully disagree. It is submitted that the recitation of "complement" in the amended claims is definite when read in light of the specification. *See, e.g.*, specification at page 18, lines 7-10. However, in order to facilitate prosecution, Applicants have amended Claims 11-14 to recite "or complete complement thereof." Therefore, reconsideration and withdrawal of the rejection are respectfully requested.

VI. Claim Rejections – 35 U.S.C. § 102(a) and (b)

Claims 1, 2 and 11-15 have been rejected under 35 U.S.C. § 102(a) as allegedly anticipated by GenBank Accession Nos: BE428765 (26 July 2000), A1861202 (19 July 1999). Office Action at pages 20-21. Applicants respectfully traverse this rejection.

In particular, the Examiner alleges that various fragments of the sequences of the GenBank Accessions are 100% identical to portions of SEQ ID NO: 1.[1] *Id.* As stated above, to facilitate prosecution Claims 1 and 2 has been amended in the present response to delete the recitation of "fragment thereof." In addition, claims 11-14 have been amended to recite that "complete complement thereof." Whatever GenBank Accession Nos BE428765 and A1861202 teach, they do not disclose SEQ ID NO: 1 or the complete complement. Nor do the cited GenBank Accessions disclose a nucleic acid molecule having between 95% and 100% identity with a nucleic acid molecule of SEQ ID NO: 1 or complete complement thereof. Absent a teaching of each and every element of the claim, *i.e.*, SEQ ID NO: 1, the references cited by the Examiner do not anticipate claims 1, 2 and 11-15 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claims 1, 2 and 11-15 under 35 U.S.C. § 102(a) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1, 2 and 11-15 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by products O3628 and O4378 of the 1993 SIGMA Chemical Catalog. Office Action at pages 21. Applicants respectfully traverse this rejection.

In particular, the Examiner alleges again that various fragments of the sequences of the recited products are identical to portions of SEQ ID NO: 1. *Id.* As stated above, to facilitate prosecution Claims 1 and 2 has been amended in the present response to delete

[1] Applicants disagree with the Examiner's assertion that "the recitation of 'comprise a region having a single nucleotide polymorphism [SNP]' does not structurally limit claim 13," as certain nucleic acid molecules will comprise a SNP.

the recitation of "fragment thereof," and claims 11-14 have been amended to recite "complete complement thereof." Whatever products O3628 and O4378 from the 1993 SIGMA Chemical Catalog teach, they do not disclose SEQ ID NO: 1 or complete complement thereof. Nor do they disclose a nucleic acid molecule having between 95% and 100% identity with a nucleic acid molecule of SEQ ID NO: 1 or complete complement thereof. Absent a teaching of each and every element of the claim, *i.e.*, SEQ ID NO: 1, the references cited by the Examiner do not anticipate claims 1, 2 and 11-15 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claims 1, 2 and 11-15 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VII. Objections to the Specification

The specification has been objected to for purportedly containing "embedded hyperlink and/or other form of browser-executable code." Office Action at page 22.

Applicants have amended the specification to replace the phrase http://www with "available on the worldwide web at." In addition, the underlining has been removed from the website citation. The citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

In light of these remarks and amendments, Applicants respectfully request withdrawal of this objection to the specification.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5085 with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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